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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): UAB-17404/22

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Signature _____

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Application Number	Filed
10/790,914	March 2, 2004

First Named Inventor: Fengxia Qi, et al.

Art Unit	Examiner
1645	Vanessa L. Ford

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☐ attorney or agent of record. Registration number 39,204
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Avery N. Goldstein
Typed or printed name

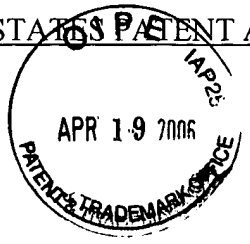
(248) 647-6000
Telephone number

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant:	Fengxia Qi et al.	Attorney Docket No. UAB-17404/22	
Serial No.:	10/790,914	Group Art Unit:	1645
Filing Date:	March 2, 2004	Examiner:	Vanessa L. Ford
For:	NOVEL LANTHIONINE ANTIBIOTIC COMPOSITIONS AND METHODS		

PRE-APPEAL BRIEF REQUEST FOR REVIEW
STATEMENT OF ARGUMENTS

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant requests review of the above-referenced application on the basis of the following remarks.

Claims 9-28 are pending in the application. Claims 9-28 are submitted for review. Currently, claims 9 and 10 stand rejected under 35 U.S.C. §102(b) over Loyola-Rodriguez et al. (of record). Claim 17 is objected to with respect to the informality of lack of capitalization and proper form of the bacterial genera; based on the amendments to claim 17 this objection is submitted to have been overcome. Claims 9-22 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Lastly, claims 17-28 stand rejected under 35 U.S.C. §112, second paragraph, for the recitation of pneumococci as an organism genus.

Remarks Directed to Rejection of Claims 9 and 10 under 35 U.S.C. §102(b) as Anticipated by Loyola-Rodriguez et al.

This rejection is originally articulated in Paper No. 20050423, page 8, section 4.

Argument 1: Loyola-Rodriguez et al. lacks an anticipatory teaching and fails to satisfy the doctrine of inherency

The rejection states:

> Rodriguez et al teach a method of treating rats against infection caused by Streptococcus mutans by administering mutacin in ht edrinking water of these animals (see the Abstract). Rodriguez et al teach that mutacin may be a candidate for use in dental caries prevention (see the Abstract). The amino acid sequence as set forth in SEQ. ID. NO: 2 would be inherent in the teachings of the prior art. Rodriguez et al anticpate the claimed invention.

(Paper No. 20050423, page 8, section 4).

The law as to inherent anticipation is well established in requiring that the missing element absolutely must be present in the thing described in the reference and not merely probable or possibly present. In *Rosco Inc. v. Mirror Lite Co.*, 64 USPQ2d 1676, 1680, the court has stated:

> Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

Applying the doctrine of inherency to pending claims 9 and 10 relative to Loyola-Rodriguez et al., Figure 1 of Loyola-Rodriguez et al. (right column, page 271) makes clear that the reference identifies a purified mutacin having a mass of greater than 6.2 kiloDaltons that is estimated to be 6.5 kiloDaltons (see abstract). Loyola-Rodriguez is silent as to a purified and isolated peptide having the sequence set forth in SEQ ID No: 2 of the pending claims or a

pharmaceutically acceptable salt, amide, ester or prodrug thereof. Likewise, Loyola-Rodriguez is submitted to be silent as to administration of a SEQ ID No: 2 peptide to a subject for the purpose of treating or preventing a gram-positive infection.

Applicant agrees that Loyola-Rodriguez identifies mutacin MT6223 as a candidate for use in dental caries prevention and administration via drinking water per the abstract. However, this teaching is immaterial under the doctrine of inherency since for Loyola-Rodriguez et al. to anticipate pending claims 9 and 10 that reference would have to have the missing descriptive material as to SEQ ID No: 2 "necessarily present", not merely probably or possibly present therein consistent with *Trintec Indus., Inc. v. Top-U.S.A. Corp.* as cited in *Rosco Inc. v. Mirror Lite Co.* above. As such, it is submitted that since the anticipatory rejection of claims 9 and 10 is devoid of an explanation how the SEQ ID No: 2 of the pending claims is necessarily present within mutacin MT6223, the outstanding anticipatory rejection is submitted to be improper.

The fact that claim 9 is drafted with the transitory open-ended phrase "comprising" is immaterial and the novelty of that claim over Loyola-Rodriguez et al. absent an assertion how SEQ ID No: 2 of the pending claims is necessarily present within Loyola-Rodriguez et al. Therefore, Loyola-Rodriguez as a prior art reference does not anticipate since the peptide of SEQ ID NO. 2 is not necessarily present within Loyola-Rodriguez et al.

Remarks Directed to Rejection of Claims 9-22 under 35 USC 112, First Paragraph.

This rejection is originally articulated in Paper No. 20051007, pages 4-8, section 6.

Argument 1: Enablement has been misapplied to pending claims

The basis of the rejection is that the specification has failed to teach or disclose the treatment of any or all infectious diseases with a composition provided according to the present invention that the claims are drawn to a method of treating or preventing all Gram-positive

bacterial infections (citing O'Brien et al. as indicating Bacillus anthracis and Clostridium botulinum as microbes used in bioterrorism). (Paper No. 20051007, page 5). The rejection states "The claimed invention broadly encompasses any infection or disease caused by any gram-positive micro-organism." (Paper No. 20051007, page 6, first full paragraph).

Applicant submits that one skilled in the art upon a review of the written description of the invention would be able to practice the invention without undue experimentation for the reasons as detailed below. Applicant respectfully submits that by applying the factors as outlined in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), an analysis is lacking as to whether each and every recited step of the claimed invention was enabled. With a finding of enablement for each and every element of the claimed invention, there is longstanding case law that holds that the resulting invention is therefore enabled.

Turning now to claim 9, the recited method involves treatment or prevention of gram-positive infection via a step that includes "administering to said subject an effective amount of a purified and isolated peptide having an amino acid sequence as set forth in SEQ ID No: 2, or a pharmaceutically acceptable salt, amide, ester or prodrug thereof." Applicant submits that the specification at page 12, line 5 – page 21, line 22 broadly teaches the compounding and administration by peptide according to SEQ ID No: 2. The spectrum of efficacy is submitted to cover enough varied bacterial genuses to support claim 9 in present form. Addtionally, claim 17 is has the narrower infective indication of staphylococci, enterococci, and pneumococci.

In regard to the insufficiency of the instant specification to achieve a level of therapeutic success, Applicant submits that testing the susceptibility of a particular microorganism to an inventive peptide is well within the talents of one of skill in the art. In support of this position, Applicant refers to the Loyola-Rodriguez reference for an exemplary teaching with respect to

Table 2 of methodologies for measuring the level of success. Additionally, the efficacy of a given medical treatment has long been held to reside within the purview of the Food and Drug Administration and not within the Patent and Trademark Office. Applicant submits that one of skill in the art certainly has the ability to test susceptibility of these pathogens towards an inventive composition without undue experimentation.

In support of enablement of pending claims 9-22, Applicants submit the un-entered declaration of co-inventor Page Caufield includes of data indicating the effectiveness of that of SEQ ID No: 2 against a variety of Gram-positive bacteria including Staph. pyogenes, Strep. pneumoniae, multiple drug resistant Staph. aureus (MDRSA), vancomycin-resistant E. faecium, and Bacillus anthracis and should have been considered (see below).

Failure to enter Response After Final Rejection was improper.

Applicant submits that the failure to enter the Response under Rule 116 was improper since the correction of typographical errors to claims 17 and 28 did not materially change the scope of the claims so as to raise new issues. With the entry of this amendment, the application is considered in condition for allowance.

Summary

Review of all the outstanding bases for rejection is hereby requested.

Respectfully submitted,

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DATE OF DEPOSIT April 19, 2006

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Janice R. Kuehn

Janice R. Kuehn